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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,329

05/24/2006

Qiu-Ping Qin

OHMAN-010

5669

32954

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12/16/2008

JAMES C. LYDON

100 DAINGERFIELD ROAD

SUITE 100

ALEXANDRIA, VA 22314

EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,329	<b>Applicant(s)</b> QIN ET AL.	
	<b>Examiner</b> JAMES L. GRUN	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-22,25-28,30,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-22,25-28,30,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/18/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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The amendment filed 18 September 2008 is acknowledged and has been entered.

Claims 33 and 34 are newly added. Claims 1-16, 23, 24, 29, 31, and 32 have been cancelled. Claims 17-22, 25-28, 30, 33, and 34 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22, 25-28, 30, 33, and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 and claims dependent thereupon are method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. These claims are indefinite because without any or sufficient active, positive steps delimiting how the method is actually practiced it is unclear what method/process applicant is intending to encompass. The claims should also clearly state each component used in the method and the relationship of the various components. With regard to the deficiencies noted above, it is unclear how one performs any measurement of PAPP-A with the method as instantly claimed because merely exposing sample to binder and measuring binder that was knowingly added detects nothing with regard to PAPP-A, free or otherwise. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim. In these claims, “the” difference or bioaffinity reaction lack antecedent basis.

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In claim 22, recitations of “the” signal lack antecedent basis. The interrelationships of the components are further unclear because it is not clear how proMBP is a subunit of a PAPP-A molecule. “Employing” or “using” or variations thereof are not valid method steps.

Claim 27 and claims dependent thereupon are method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. These claims are indefinite because without any active, positive steps delimiting how the method is actually practiced it is unclear what method/process applicant is intending to encompass. The claims should also clearly state each component used in the method and the relationship of the various components. With regard to the deficiencies noted above, it is unclear how one performs any measurement of PAPP-A with the method as instantly claimed in dependent claim 30 because merely exposing sample to binder and measuring binder that was knowingly added detects nothing with regard to PAPP-A, free or otherwise. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim.

Applicant's arguments filed 18 September 2008 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 27 and 28 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Conover et al. (US 6,500,630) for reasons of record.

Applicant's arguments filed 18 September 2008 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the disclosure of Conover et al. at column 4 could have several interpretations. This is not in dispute. However, notwithstanding applicant's assertions to the contrary, the disclosure of Conover et al. is not limited to the single of the alternative interpretations as argued by applicant in view of the disclosures regarding immunization with uncomplexed PAPP-A and the additional passage noted in the rejection of record at column 6: "Antibodies having affinity for PAPP-A are identified in a positive selection. Antibodies identified in such a selection can be negatively selected against PAPP-A/proMBP, to identify antibodies having specific binding affinity for epitopes of PAPP-A that are not accessible in the specific complex of PAPP-A and proMBP." Applicant's assertions regarding the lack of specificity of an enzymatic antibody capture assay for the detection of free PAPP-A were not found persuasive in view of the above noted teachings regarding antibody selection and the well known inhibition of PAPP-A enzymatic activity when complexed with proMBP (see e.g. cols. 4 and/or 5). The rejection is maintained for the reasons of record.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Overgaard et al. (JBC 275: 31128, 2000) teach proMBP as an inhibitor of PAPP-A enzymatic activity.

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Overgaard et al. (WO 00/54806 or US 7,115,382) teach the production of monoclonal antibodies specific for pregnancy-associated plasma protein-A (PAPP-A) not complexed with pro major basic protein (proMBP) and the use of the antibodies for detection of uncomplexed PAPP-A in a sample (in US 7,115,382, see e.g. col. 5 and Claim 1).

Christiansen et al. (Clin. Chem. 46: 1099, 200) teach detection of angiotensinogen /proMBP complexes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./

James L. Grun, Ph.D.

Examiner, Art Unit 1641

December 16, 2008

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/Ann Y. Lam/

Primary Examiner, Art Unit 1641

December 11, 2008